Exhibit 189
(Filed Under Seal)

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK

by and through ERIC T. SCHNEIDERMAN,
Attorney General,

Plaintiff,

v.

ACTAVIS, PLC, and

FOREST LABORATORIES, LLC

Defendants.

Case No. 14-CV-7473 (RWS)

FILED UNDER SEAL

DECLARATION OF ERNST R. BERNDT, Ph.D.

November 5, 2014

PX64

I. QUALIFICATIONS

1. My name is Ernst R. Berndt. I am the Louis E. Seley Professor in Applied Economics at the Sloan School of Management, Massachusetts Institute of Technology ("MIT"). I have been a Professor of Applied Economics at MIT since 1980. From 1992 to 1995, I served as Area Head of the Applied Economics, Finance and Accounting faculty area at the MIT Sloan School of Management. I am also a Research Associate at the National Bureau of Economic Research ("NBER"), and from 2000 to 2010, served as Director of its Program on Technological Change and Productivity Measurement. Between 2003 and 2013, I was also Co-Director of the Biomedical Enterprise Program, a joint degree-granting program at the Harvard-MIT Division of Health Sciences and Technology and the MIT Sloan School of Management. I am an elected Fellow of the Econometric Society, and have been awarded an honorary doctorate degree from Uppsala University in Sweden. I am the author or co-author of a number of books, including a well-known textbook, *The Practice of Econometrics: Classic and Contemporary*. I have also served on the editorial boards of a variety of economic, econometric and statistical journals. Currently I am on the editorial board of Health Affairs. My professional qualifications, including my publications, are described in my curriculum vitae, which is attached as Appendix A.

2. A major focus of my academic research over the last twenty years has been on health economics and, more specifically, on the economics of the pharmaceutical, vaccine, medical device and biotechnology industries. One particular area I have studied substantially has been the impact of generic pharmaceuticals on brand-name prescription drugs. Some recent examples of this research include (1) a published manuscript that reviews the history of generic

entry and price competition in the United States since 1984 and critically analyzes the important developments in the economics literature on this subject since passage of the Hatch-Waxman legislation[1]; (2) a chapter on pricing and reimbursement in United States pharmaceutical markets in a handbook on the economics of the pharmaceutical industry[2]; (3) an NBER working paper that examines sales and pricing by payer type[3] for six drug molecules for which patent exclusivity in the United States initially lapsed between 2009 and 2013[4]; and (4) an NBER working paper that examines the impact of loss of exclusivity on the prices and utilization of specialty drugs between 2001 and 2007.[5]

3. In addition, I have studied the impacts of marketing (i.e., direct-to-consumer advertising, medical journal advertising, physician detailing, and physician sampling) on sales of pharmaceutical drugs, and on switches of drugs from prescription-only to over-the-counter status. I have also examined issues of price measurement, such as the construction of price indexes for the treatment of certain illnesses, including mental health conditions and diabetes. I have conducted research on the steps by which promising medicines move from pre-clinical and clinical development phases through the U.S. Food and Drug Administration ("FDA") approval process; factors affecting the differential rates of diffusion of new medicines across different

[1] Berndt, E.R. and Aitken, M.L., "Brand loyalty, generic entry and price competition in pharmaceuticals in the quarter century after the 1984 Waxman-Hatch legislation," *The International Journal of the Economics of Business*, 18(2):177-201, July 2011.

[2] Berndt, E.R. and Newhouse, J.P., "Pricing and reimbursement in U.S. Pharmaceutical Markets," Cambridge, MA: National Bureau of Economic Research, Working Paper No. 16297, August 2010; revised version in Danzon, P.M., Nicholson, S., eds., *The Economics of the Biopharmaceutical Industry*, New York: Oxford University Press, 2012, Chapter 9, pp. 201-265.

[3] I.e., Medicare Part D, Medicaid, other third party payers, or the patient himself or herself via cash payment.

[4] Aitken, M. L., Berndt, E.R., Bosworth, B., Cockburn,, I.M., Frank, R.G., Kleinrock, M., and Shapiro, B.T., "The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity", Cambridge, MA: *National Bureau of Economic Research*, Working Paper No. 19478, October 2013.

[5] Conti, R.M., and Berndt, E.R., "Specialty Drug Prices and Utilization after Loss of U.S. Patent Exclusivity, 2001-2007", Cambridge, MA: *National Bureau of Economic Research*, Working Paper No. 20016, March 2014.

countries; advance purchase commitments that create incentives to develop vaccines for diseases endemic in poor countries; and the globalization of clinical trials into emerging economies.

4. In addition to my academic research, from 1996 to 2000 I served as an appointed representative of the American Economic Association to the Economics Advisory Committee of the U.S. Census Bureau, serving as the Committee's co-chair from 1999 to 2000. From 1991 to 2000, I was a member of the Advisory Committee on Service Statistics at Statistics Canada and, between 1999 and 2001, I was a panel member of the U.S. Committee on National Statistics and the National Academy of Sciences' Panel on the Conceptual, Measurement and Other Statistical Issues in Developing Cost-of-Living Indexes. From 2000 to the present, I have served on the U.S. Federal Economic Statistics Advisory Committee, an interagency committee jointly formed by the U.S. Bureau of Labor Statistics, the U.S. Census Bureau, and the U.S. Bureau of Economic Analysis. From 2000 to 2004, I was its first Chair. I have been a review panel member for the Methodology, Measurement, and Statistics program at the National Science Foundation, and recently finished a term as a member of the Advisory Committee of the Social, Behavioral and Economic Sciences Directorate of the National Science Foundation. From October 2003 through June 2004, I served on an unpaid Intermittent Detail to the FDA, Office of the Commissioner and, in 2006, I was an uncompensated Special Government Employee at the FDA, Office of the Commissioner, a position to which I was reappointed. Since 2011, I have been a member of the Committee on Science, Technology and Economic Policy at the National Academy of Sciences. Currently I chair the Advisory Committee to the Bureau of Economic Analysis in the U.S. Department of Commerce.

5. I have been qualified as an expert in a number of cases, including in the pharmaceutical industry. See Appendix B for a list of cases in which I have testified at either

trial or deposition in the past five years. I also have served as an Independent Expert to two U.S. district court judges, Judge Patti B. Saris and Judge William G. Young, both of the District of Massachusetts.

II. ASSIGNMENT AND COMPENSATION

6. I have been retained by New York State to provide an expert opinion, and, as needed, testimony, in *State of New York v. Actavis, PLC, et al.* (S.D.N.Y. Case No. 14-CV-7473) (the "Litigation").

7. In particular, New York State has asked me to opine on:

a) The relevant product and geographic markets to employ in this case for purposes of antitrust analysis;

b) The expected effect on competition of the "hard-switch" strategy, or some substantially equivalent strategy, and (to the extent relevant) the extent to which other possible variants of the hard-switch strategy, such as "limited distribution," would affect my opinions;

c) Whether there are any business justifications for the hard-switch strategy, other than the exclusion or foreclosure of generic competition;

d) The merits of Forest's assertion that the granting of the relief sought by the State of New York in the Litigation would constitute socially harmful economic "free-riding"; and

e) Other important economic considerations related to or material to the above opinions.

8. I am being compensated at a rate of $675 per hour for my expert work on this Litigation, including testimony. My compensation does not depend on the opinions I provide.

III. DOCUMENTS CONSIDERED

9. In forming the opinions stated in this Declaration, I had access to a large number of documents filed, served, or produced in connection with the case of State of New York v. Actavis, PLC, et al. (S.D.N.Y. Case No. 14-CV-7473) (the "Litigation"), in addition to a variety of publicly available or widely available documents or information sources. These documents

and data sources to which I had access are disclosed in Appendix C. To the extent documents or data were relied on in connection with the formation of my opinions, I cite to those documents or data in this Declaration. I reserve the right to amend this Declaration, and/or the opinions expressed in it, as information that was not known or considered in the formation of such opinions becomes available.

IV. SUMMARY OF OPINIONS

10. Following is a summary of the opinions I have reached concerning the facts of this Litigation, as discussed further in this Declaration:

(i) First, I conclude NMDA antagonists comprise a relevant product market for purposes of antitrust analysis, due to factors including data suggesting that they have a low cross-elasticity of demand with the one other major category of drugs prescribed for Alzheimer's Disease, the AChEIs (also referred to as "CIs").[6] I also conclude that the United States is the relevant geographic market for antitrust purposes.

(ii) Second, I conclude that that the "forced switch" or "hard switch" described in the Complaint—that is, the removal of Namenda IR tablets from the market prior to the availability of a generic form of Namenda IR ("generic memantine (IR)")—can be expected to materially impair competition in the market for NMDA antagonists. This material impairment of competition will occur for the following reasons:

- Sellers of generic memantine (IR) will have substantially more difficulty successfully entering the market for NMDA antagonists than would have been the case absent the forced switch. Under the forced switch scenario, at the time of loss of exclusivity ("LOE") of the patent on Namenda IR that is licensed by Forest, there will be no widely distributed branded version of memantine to which generic memantine (IR) is AB-rated. This will hinder generic penetration, because the generic companies' usual, and most efficient, means of entry is through generic substitution by pharmacists, coupled with state generic substitution laws and generic-substitution policies of payers (health insurers and pharmacy benefit managers). The hard switch strategy will deny would-be generic competitors effective access to this form of entry. (This is particularly debilitating in a multi-generic

[6] Abbreviations and defined terms, if not defined herein, take the definitions (if any) given for them in the Complaint in the Litigation.

market, like this one is likely to be, where other possible means of entry—such as aggressive marketing by generic firms—are foreclosed to generics due to free-rider effects.)

- Of the sizeable population that is taking Namenda IR at the time when the forced switch occurs,[7] nearly all patients will switch to Namenda XR, and the majority of those patients will remain with Namenda XR, even though almost all of them would have switched to generic memantine (IR) absent the forced switch, due to substitution at the pharmacy. Thus, these patients, together with their health plans, will be deprived of a cost-effective and practical means of selecting their preferred (drug, cost) combination.
- Although I have not arrived at a precise "point estimate" of the exact harm to consumers and health plans, a useful approximate calculation was run using [redacted] and its economic expert Pierre-Yves Cremieux. The result of this simple calculation is that, for the calendar years 2016-18 inclusive, health plans will pay about [redacted] more for NMDA antagonist medication under the hard-switch scenario than they would have paid under the conventional scenario, and Alzheimer's Disease sufferers will pay approximately [redacted] more than would have been the case absent the hard switch.

(iii) I also conclude that the existence of "limited distribution" of Namenda IR tablets that has been announced by Forest does not change any of the above conclusions, because these distribution channels are expected to cover a relatively small quantity of the medication, and/or require patients or physicians to absorb high frictional costs to access these channels. Forest's suggestion that the generic substitution laws of some states may allow pharmacists in those states to substitute generic memantine (IR) in place of branded Namenda XR also does not significantly affect my analysis, for reasons discussed below.[8]

(iv) I conclude that there is no legitimate business justification for Forest to undertake the hard switch—that is, no business justification apart from the exclusion of generic competition. Removing Namenda IR from the market prior to generic entry, [redacted] requires a short-term sacrifice of [redacted] Forest's explanations about undertaking the hard switch to preserve "focus," and to realize manufacturing synergies, do not make economic sense, and I

[7] Here, and elsewhere, I speak of the migration of patients from Namenda IR to Namenda XR when the forced switch occurs. However, one must read "occurs" somewhat broadly. Because Forest has already announced its intention to effectuate the hard-switch strategy, it stands to reason that some switches from Namenda IR to Namenda XR that are being caused by the hard switch are occurring already, in anticipation of the unavailability (or limited availability) of Namenda IR.

[8] See, e.g., Decl. of Pierre-Yves Cremieux (Oct. 21, 2014), at para. 31.

have seen no evidence that would lead me to believe these are not post-hoc rationalizations. Moreover, there are other ways to achieve these goals that do not involve harming generic competition.

(v) The assertion that a refusal to countenance Forest's desire to soften its "patent cliff" for Namenda IR will encourage "free riding" by generic firms is misleading. It improperly makes incentive arguments concerning future R&D decisions in other markets to justify anticompetitive present-day conduct in the NMDA antagonist market. It also ignores one half of the policy bargain implicit in the patent system and the Hatch-Waxman legislation.

V. BACKGROUND

Kefauver-Harris and Hatch-Waxman Legislation

11. The modern history of U.S. legislative and regulatory developments regarding brand and generic drugs began with the Kefauver-Harris Drug Act in 1962, also known as the Kefauver-Harris Amendments to the 1938 Food, Drug and Cosmetic Act.[9] This was the law that first required sponsors of New Drug Applications ("NDAs") to document evidence of both safety and efficacy—not just safety—with the U.S. Food and Drug Administration ("FDA"). Among its many notable provisions, the law prohibited the marketing of inexpensive-to-manufacture generic drugs as expensive drugs under new trade names, and prevented the use of generic names that were obscure and difficult to remember—a practice that manufacturers allegedly employed to diminish generic substitution. For purposes of this Declaration, the Kefauver-Harris Drug Act Amendments of 1962 are notable for clarifying distinctions between brand and generic drugs and regulating their marketing.

12. A subsequent important legislative development was the Hatch-Waxman Drug Price Competition and Patent Term Restoration Act of 1984, frequently referred to as a "grand

[9] Much of the material in this section of my Declaration draws on material discussed in Ernst R. Berndt and Joseph P. Newhouse, "Pricing and Reimbursement in U.S. Pharmaceutical Markets," ch. 8 in Patricia M. Danzon and Sean Nicholson, eds., *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, New York: Oxford University Press, 2012, pp. 201-265

compromise" between branded drug manufacturers, who (among other things) sought an extension of their patent terms to account for the time a patented drug has spent under regulatory review; and generic manufacturers, payers and consumers, who desired a transparent, expeditious regulatory process that provided affordable access to generic medications on a timely basis. More specifically, Hatch-Waxman established the Abbreviated New Drug Application ("ANDA") pathway to marketing a generic drug. Unlike the filer of an original NDA, the filer of an ANDA only needed to establish "bioequivalence" with the reference (usually, branded) drug, thus eliminating the need for follow-on generics to establish safety and efficacy anew through costly clinical trials.[10] When a generic manufacturer submitted an ANDA and successfully established bioequivalence with the originator drug (called the Reference Listed Drug, or "RLD")—and had been found to comply with current "Good Manufacturing Practices"—the FDA was authorized to approve the ANDA.

13. Along with ANDA approval of a given generic drug, the FDA assigns the generic an "A" or "B" rating. "A" ratings generally mean that the generic is "bioequivalent" to the RLD (or branded drug). One type of A rating—the type most relevant here—is the "AB" rating. An AB rating to the branded drug means that "any actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence."[11] Here, "bioequivalence" means, essentially, identical active ingredients, and absorption profile.

14. When filing an ANDA, the applicant must make one of four certifications: (i) that the drug has not been patented; (ii) that the patent has already expired; (iii) that the generic drug

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[10] For further discussion, see Gerald J. Mossinghoff, "Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process," *Food and Drug Law Journal* 1999, 54(2):187-194.

[11] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm, most recently visited Nov. 5, 2014.

will not go on the market until the patent expires (and the date on which expiry will occur); or (iv) that the patent is not infringed or is invalid. These certifications are commonly referred to as the paragraphs I, II, III, and IV certifications. If a generic company certifies a Paragraph IV notice, it must notify the patent owner, who has 45 days in which to file a patent infringement action and then another thirty months of exclusivity before an ANDA can be approved, unless there is a final appellate decision earlier favoring the generic entrant.[12]

15. If the Paragraph IV filer is successful in its litigation challenging the patent owner, it is granted 180 days of exclusivity, during which time it will be the only approved ANDA entrant for that molecule dosage formulation. However, only the *first* Paragraph IV filer obtains this limited exclusivity. In other words, the first Paragraph IV filer is given the right to be the only generic entrant for a 180-day period. The brand-name drug will generally still be sold during this time. However, because the branded drug usually has a very high price, reflecting its (sunsetting) patent monopoly, as a practical matter it is much more profitable to be the only generic company in the market than to have to compete with many other generics.[13]

16. During the 180-day exclusivity period for the first Paragraph IV filer, the branded patent owner can enter into a licensing agreement with another generic distributor to market the molecule dosage formulation under the brand's NDA; this is commonly called an "Authorized Generic entry."

17. In terms of pricing, if because of a successful Paragraph IV challenge a single generic entrant competes with the brand for 180 days, typically the generic will be priced at a 10-

[12] Mossinghoff [1999], *op. cit.*, p. 189.

[13] In the event that there are multiple Paragraph-IV filings made on the same day, the filers may share 180-day exclusivity for that molecule formulation. This situation is not as uncommon as one might think, because the 180-day exclusivity is lucrative, so multiple filers will sometimes file on the first day when such filing is permitted.

20% discount off the brand. If Authorized Generic entry occurs making the market a triopoly for 180 days (the brand, the independent generic, and the authorized generic), the average generic price will fall another 10-20%. However, after the 180-day exclusivity expires, typically massive generic entry occurs (with the number of entrants depending in part on the dollar sales volume of the brand prior to LOE), leading to generic prices that average 10-20% of the pre-LOE brand price.[14]

18. Thus, the right to be the exclusive generic for a 180-day period is a valuable one. It is well-understood that this fact was critical to the policy intent behind the Hatch-Waxman scheme: Under the scheme, generic manufacturers are offered the "prize" of 180-day generic exclusivity, in order to induce more aggressive generic entry—and, in particular, to induce (costly) court challenges by generics to brand-name companies' patents that are perceived as weak.

19. The 1984 Hatch-Waxman law, and associated bioequivalence rating procedures, were greatly strengthened by the fact that individual states enacted complementary legislation specifying conditions under which pharmacists could—without physician approval—dispense a generic drug in response to a prescription that names the branded drug to which the generic is AB-rated. The premise of these laws—referred to in this Declaration as "state generic substitution laws"—is that a pharmacist typically has an incentive to identify the cheapest source of supply and pass along at least part of the savings to the consumer/payer.[15]

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[14] For further discussion, see *Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, A Report of the Federal Trade Commission, August 2011; and Aitken, Berndt, Bosworth et al. [2013], *op. cit.*, and the references cited therein.

[15] Alison Masson and Robert L. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Substitution Laws*, Washington DC: Staff Report of the Bureau of Economics, Federal Trade Commission, October 1985, p. 1 (footnotes deleted).

The results of Hatch-Waxman

20. In the first decade after the passage of the Hatch-Waxman law, the increased usage of generic drugs was palpable, but modest. But the success of generic drugs under the Hatch-Waxman scheme has greatly increased since then, to the point where now it cannot be denied that the legislation has accomplished its objectives remarkably well.

21. One way to measure generic penetration for the overall US prescription drug market (rather than just for the leading selling brands losing patent protection) over time is to compute the generic share of all prescriptions dispensed (brand, branded generic and non-branded generic), where generic is the sum of branded generic and non-branded generic.[16] In Table 1 below I report five-year trends in the generic share of total prescriptions, 1984-2009, as reported in Berndt and Aitken [2011], Figure 2, based on IMS Health National Prescription Audit archives (1984-2004) and IMS Health National Sales Perspectives (2005-2009).[17]

TABLE 1: FIVE-YEAR TRENDS IN GENERIC SHARE OF TOTAL PRESCRIPTIONS, 1984-2009

YEAR	GENERIC SHARE OF TOTAL PRESCRIPTIONS
1984	18.6%
1989	32.0%
1994	36.0%
1999	49.7%
2004	56.4%
2009	74.5%

[16] Branded generics are defined by IMS Health as non-originator products that are either: (i) novel dosage forms of off-patent products; (ii) on patent with a trade name, but a molecule copy of an originator product; (iii) off-patent with a trade name; or (iv) off-patent without a trade name and from a single source or co-licensed. In the IMS Health classification scheme, an example of (i) is Concerta™, an extended release formulation of methylphenidate hydrochloride, the active ingredient in the off-patent drug Ritalin™ used to treat attention deficit hyperactivity disorder, while the opioid analgesic Oxycontin™ is an example of (iii).

[17] Ernst R. Berndt and Murray L. Aitken, "Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation", *International Journal of the Economics of Business* July 2011, 18(2):177-201. Figure 2 is on page 181.

As Table 1 shows, at the time of passage of the 1984 Hatch-Waxman legislation, the generic share of total prescriptions was 18.6 percent, which then increased to 32 percent in 1989, 36 percent in 1994, then jumped to 49.7 percent in 1999 (15 years after passage of Hatch-Waxman) and 56.4 per cent in 2004, and rose very sharply to 74.5 percent in 2009. Another measure of generic penetration is the generic "efficiency rate," the fractional generic volume sold for those molecules for which generics are available. In recent years, this number has exceeded 90%.

State generic substitution laws

22. As noted above, state generic substitution laws have also played an important role in this process. Generic substitution laws are determined by individual states, and can differ among states. Some states, like the State of New York, have chosen to make generic substitution of AB-rated generics mandatory at the pharmacy, unless the physician specifies otherwise (usually, by stating "dispense as written" on the prescription form). Other states have made generic substitution by pharmacists of AB-rated generics permissive, i.e., allowable at the discretion of the pharmacist—again, unless the physician specifies otherwise. States may have other nuances to their generic substitution rules. Notwithstanding this diversity in regulatory approaches state-by-state, as noted above, generic efficiency rates are now above 90% nationwide. Specifically, more recent data on generic share of prescriptions[18] documents continued increases in the share of generic prescriptions and the generic efficiency rate. For 2010 through 2013, the generic (unbranded generic plus branded generic) share of prescriptions

[18] IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013*, April 2014, Appendix 9, p. 51.

rose to 78 percent (2010), 80 percent (2011), 84 percent (2012) and 86 percent (2013), with the 2013 generic efficiency rate being 95%.[19]

VI. RELEVANT MARKET

23. As I understand it, in this Litigation the State of New York alleges that the relevant product market, for purposes of antitrust analysis, is the market of N-methyl-D-aspartate (NMDA) receptor antagonists (i.e., medicines with memantine hydrochloride as the active pharmaceutical ingredient) ("NMDA antagonists"); and the State of New York further alleges that the relevant geographic market for the sale of NMDA antagonists is the United States.

24. The Supreme Court has stated that, for antitrust purposes, a "relevant market" is made up of "commodities reasonably interchangeable by consumers for the same purposes."[20] Moreover, as I understand it, the reasonable interchangeability of a set of products is not dependent on the similarity of their forms or functions. Instead, "[s]uch limits are drawn according to the cross-elasticity of demand for the product in question – the extent to which purchasers will accept substitute products in cases of price fluctuation and other changes."[21] To inform the decision of how to define the relevant market in this case, I therefore examine alternative treatments approved by the FDA to treat dementia symptoms of the Alzheimer's type. (Currently, the available approved medicines only treat symptoms as they progress, and none is curative).

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[19] Research I have conducted with collaborators has shown that generic efficiency rates are slowest and lowest for Medicaid payers, and are generally highest for commercial third party private payers, with cash and Medicare Part D being in between. Aitken, M. L., Berndt, E.R., Bosworth, B., Cockburn,, I.M., Frank, R.G., Kleinrock, M., and Shapiro, B.T., "The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity", Cambridge, MA: *National Bureau of Economic Research*, Working Paper No. 19478, October 2013.

[20] *United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 395, 76 S. Ct. 994, 100 L. Ed. 1264 (1956).*

[21] *George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc., 508 F.2d 547, 552 (1st Cir. 1974).*

Reasonable interchangeability of use

25. FDA-approved drugs to treat the dementia symptoms of Alzheimer's Disease include medicines with one of two mechanisms of action. Three of the approved molecules[22]—donepezil hydrochloride (brand name Aricept), galantamine (Razadyne), and rivastigmine (Exelon)—belong to the same class and have a similar mechanism of action; they are frequently called cholinesterase inhibitors ("CIs"), or acetylcholinesterase inhibitors ("AChEIs").[23] According to Dr. James J. Lah, M.D., Ph.D., "these drugs reduce the breakdown in the brain of a chemical called acetylcholine, a chemical messenger that transmits information between nerve cells."[24] As the disease progresses, the efficacy of this class of drugs decreases. Accordingly, CIs are most often prescribed for mild to moderate dementia symptoms of Alzheimer's Disease.[25] Namenda IR (memantine) and Namenda XR are NMDA antagonists, each containing the memantine molecule. Dr. Lah notes that Namenda (memantine) has a different mechanism of action than the CIs: "Namenda thwarts the overstimulation of glutamate, an amino acid that excites nerves, and in excess, is a powerful nerve-cell killer. Excessive glutamate activity in mid-stage and late-stage Alzheimer's patients is believed to interfere with neurotransmission, contributing to neurodegeneration. Namenda is most often prescribed for moderate- through late-stage Alzheimer's."[26]

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[22] I understand that a fourth FDA-approved NMDA antagonist -- tacrine hydrochloride (brand name Cognex) -- was discontinued in the U.S. market in 2012.

[23] *Drug Facts and Comparisons*, 2011 Edition, St. Louis, MO: Wolters Kluwer Health, pp. 1606-1623.

[24] Declaration of James J. Lah, M.D., Ph.D., September 8, 2014, ¶6, p. 2.

[25] Id.

[26] Declaration of James J. Lah, M.D., Ph.D., September 8, 2014, ¶7-8, p. 2.

26. Because they have distinct mechanisms of action, a combination of one CI and one oral formulation of memantine is commonly prescribed for patients with moderate to severe Alzheimer's Disease symptoms.[27] Aricept has been FDA-indicated for all three forms of Alzheimer's Disease—mild, moderate, and severe—since October 2006.[28] Namenda, by contrast, is indicated only for the moderate and severe forms of the disease.[29] As Forest noted in [redacted][30] Indeed, approximately 70% of patients taking Namenda also take a CI medication.[31]

27. For quite some time the donepezil molecule has been the most prescribed CI in the US. Presumably because donepezil is the most prescribed CI, and because combination therapy with an oral formulation has proven to be an effective treatment, Forest has announced it

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[27] *See* Meury Inv. Hearing, Exh. 6, p. 1, in which Namenda XR promotional material states, "NAMENDA XR (memantine hydrochloride) works in a different way than other Alzheimer's disease medications. That's why adding NAMENDA XR to an AChEI is effective – 2 different treatments working in 2 different ways to treat moderate to severe Alzheimer's disease" (bold text in original). In addition, a survey of 233 physicians conducted in September 2013 and sponsored by Forest found that only 5% of physicians prescribed Namenda as a monotherapy, while 28% prescribed Namenda as part of a combination therapy. Hence, while Namenda may be a potential substitute with a CI such as donezepil for a very small share of prescribers, for a much larger share of prescribers (more than five times larger), Namenda is a complement. See Declaration of Pierre-Yves Cremieux, October 21, 2014, ¶39, p. 15 and notes 60-61.

[28] FDA Press Release P06-168, "FDA Approves Expanded Use of Treatment for Patients With Severe Alzheimer's Disease," Oct. 13, 2006, available at http://www.fda.gov/newsevents/newsroom/pressannouncements/2006/ucm108768.htm (last visited Nov. 1, 2014).

[29] Highlights of Prescribing Information, Namenda, FDA Reference ID 3394954 (revised 10/2013).

[30] FRX-NY-01648212, at -01648216.

[31] *See, e.g., id.*

has submitted a New Drug Application to the FDA for a combination fixed-dose product consisting of donepezil and Namenda XR, seeking the brand name Namenda FDC.[32]

28. Based on the above facts, I have no reason to believe that memantine and CIs are "reasonably interchangeable." Indeed, if the price of memantine were to increase significantly—the usual thought experiment one performs in testing the contours of an antitrust market—the question of whether memantine patients would "substitute" by switching to donepezil would not even make sense for 70% of them, because they would already be taking donepezil. [redacted] [33]

Cross-elasticity of demand

29. Moreover, in this instance, history provides a "natural experiment" concerning the cross-elasticity of demand between these two classes of drugs, which supports a market definition limited to NMDA antagonists.[34]

30. In November 2010, Aricept lost exclusivity in the United States. For six months thereafter, there was a single generic donepezil entrant. Generic sales from multiple sources then

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[32] Forest Laboratories' CEO Discusses F4Q 2014 Results – Earnings Call Transcript, Apr. 29, 2014, available at http://seekingalpha.com/article/2174863-forest-laboratories-ceo-discusses-f4q-2014-results-earnings-call-transcript?part=single, last visited Nov. 11, 2014 ("[w]e filed two new fixed dose combinations for approval [during the preceding quarter], Namenda XR plus Donepezil and Bystolic plus Valsartan."

[33] *See* Meury Inv. Hearing Exh. 7 (FRX-NY-01648212, at -216) ("The Azheimer's market consists of only two classes of drugs that provide symptomatic treatment" [referring to AChEIs and NMDA antagonists]; "As Aricept is indicated for mild patients it is usually initiated first Namenda is usually added when the patient progresses to the moderate stage of the disease . . .").

[34] Cross-elasticity of demand is a measure of the degree to which one product, or group of products, has its prices constrained by the availability of another product or group of products. In particular, it is the fractional amount by which the quantity of one product (or group) that is sold rises, divided by the (small) fractional increase in the price of the other product (or group) being considered—assuming only the price of the second product changes. (In simple terms, if a 1.0% increase in the price of Coke drives Coke drinkers to buy Pepsi instead, such that the quantity of Pepsi sold increases by 0.5%, then the cross-elasticity of demand between the two products is 0.5% divided by 1.0%, or ½.

commenced in June 2011. As described in Aitken, Berndt, Bosworth et al. (2013),[35] the first generic entrant typically prices its drug moderately below the pre-exclusivity price of the branded drug; and subsequent generic entry typically drives generic prices to dramatically lower levels. Therefore, the entry of generic donepezil represents a relevant natural experiment: First, the donepezil price would have dropped modestly relative to Namenda—which is equivalent to an increase in the price of Namenda *relative to* donepezil. Then, six months later, this effect would have been magnified, driving the relative price of Namenda substantially higher. If the cross-elasticity of demand between the two products were high, one would expect Namenda sales to tick downward slightly with the slight increase in Namenda's relative price, and tick downward markedly with the large increase in Namenda's relative price, as consumers and health plans began to favor the cheaper donepezil substitute.[36] [redacted]

[35] Op. cit., Table 1.

[36] I note that Forest's expert Pierre-Yves Cremieux cites to the same natural experiment at Chart 5 of his Declaration. However, [redacted] —presumably, a much smaller number of outstanding *prescriptions*, since each prescription covers many days of therapy. Thus, assuming that the typical patient represents 90 days of therapy per quarter, Crimieux's sample is almost unbelievably small: not just a single employer's health plan, but somewhere between 4 and 16 *individuals* covered by that plan. The bumpy up-and-down quality of Crimeux's "days of therapy" line may reflect individual patients moving onto and off of the drug.

[redacted]

31. [redacted]

[30] FRX-NY-01577325, attachment FRX-NY-01577329, at slide 4

[redacted] This evidence provides striking support for the assertion that the cross-elasticity between donepezil and Namenda is vanishingly small, and might even be slightly negative.[39]

32. The factual interpretation of Figure 1 is supported, [redacted] [40]

Forest's other arguments concerning market definition lack merit

33. While Forest's expert Jerry A. Hausman takes no position on market definition,[41] Forest's other expert, Pierre-Yves Cremieux, writes that defining a market composed of NMDA antagonists exhibits "flawed" reasoning, which "neglects to examine how Namenda and AChEI drugs are used to treat patients."[42] Citing Optum Health retrospective claims data for January 1998-March 2013, Cremieux notes that Nemanda patients have a history of switching among different Alzheimer's drugs, which Cremieux interprets as evidence of substitutability.

34. First, Cremieux notes that "of the 54,165 patients with at least one filled Namenda prescription, 61.1 percent had used another Alzheimer's drug prior to their first Namenda

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[38] Declaration of Pierre-Yves Cremieux, October 21, 2014, ¶45, p. 19.

[39] That opportunities for Namenda users to substitute to lower-cost generic donepezil were ample is clear from - [redacted] FRX-NY-01577329, slide 3.

[40] FRX-NY-01634296, at -297. *See also*, FRX-NY-01578889, at -892 to -893.

[41] Declaration of Jerry A. Hausman, October 21, 2014, note 1, p. 2.

[42] Declaration of Pierre-Yves Cremieux, October 21, 2014, ¶33, p. 13.

prescription, with the most common single drug being Aricept (43.8%)" followed by other CIs.[43] However, there is no reason to believe this evidence is relevant to the question of antitrust market definition. It is obvious that the most likely reason why patients with Namenda prescriptions would have used another Alzheimer's drug prior to using Namenda is that the AChEIs are more commonly used for the early stages of the illness, and Namenda is then prescribed in the moderate and advanced stages, either alone or (perhaps more commonly) in combination with the CI.[44] This relationship does not suggest that that the two products are good—or bad—substitutes for one another, but merely suggests that they constitute sequential steps from a common progression in time. To use an analogy, if one learns that 90% of American men who retain the services of a wedding planner have previously gone shopping for engagement rings, the most likely reason is that people get engaged before they get married, not that wedding planning services are a good substitute for the sale of diamond rings. Thus, I believe Dr. Cremeiux is drawing an unwarranted inference from these data.

35. Citing the same data source, Dr. Cremieux notes that 30.7% of Namenda patients "used another Alzheimer's drug after their last Namenda prescription."[45] Here, too, the inference seems to be that people switch frequently between Namenda and CIs. Here, the point being made seems erroneous, because Dr. Cremieux does not indicate how many of the 30.7% of patients were already using another Alzheimer's drug before they stopped using Namenda, but it is difficult to tell because Dr. Cremieux's expression of his point is unclear. If a patient is on combination Namenda/CI therapy (as 70% of Namenda users are), and that patient filled one

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[43] Ibid, op. cit., ¶42, p. 16.

[44] *See, e.g.*, Meury Inv. Hearing Exh. 7 (FRX-NY-01648212, at -216).

[45] Cremieux Decl., para. 43.

Namenda prescription in January 2013, just before the end of the period studied, then filled a CI prescription in February 2013, and then the period ended—would the January Namenda fill be counted as the person's "last Namenda prescription"? More broadly, how is the fact that a person's "last" Namenda prescription is indeed his last established? These critical questions are left unanswered by Dr. Cremieux.

36. Assuming that this ambiguity was handled in some reasonable way that I cannot extract from Dr. Cremeiux's Declaration, the data still do not necessarily speak to antitrust market definition. A key feature of the data cited by Cremieux is that, assuming there really was a "switch" from Namenda to a CI (it is far from clear that is what happened), such switching does not speak to market definition unless it is the type of switching contemplated by demand elasticities—i.e., switching in response to a price increase, or some other sort of exogenous source of scarcity. A very common type of switching is not of this sort at all: People switch from one medication to another frequently, because the first medication is either not working well, or is giving them unpleasant side-effects. In such a case, one cannot conclude that the two are substitutes. They may be, or not, depending on the situation. To take a medical example, suppose I go to my doctor complaining of chest pain. He believes the most likely explanation is reflux esophagitis, and gives me an acid reducer, Prilosec. I take the Prilosec for a month, but the pain continues. Now, my doctor concludes that it must not be reflux after all, but is more likely angina of the heart. So he prescribes Cardizem, a heart medication, and it works well. The pain goes away, and I remain on Cardizem. In prescription data of the kind Cremieux cites, I will appear only as a person who switched from Prilosec to Cardizem. This does not mean I regard the two as substitutes, especially for antitrust market definition purposes.

37. Both examples share a common feature: The cessation of one drug and the commencement of the other share a common causal link other than a price increase or other external imposition of "scarcity"—which is what cross-elasticities aim to measure. This is why the "switching" data cited by Cremeiux (if that is what it is, given the ambiguities already discussed) is not a good indicator of cross-elasticities, while the natural experiment cited above is.

38. Finally, I understand that Forest has asserted in some of its legal papers that single-molecule markets are disfavored by courts.[46] Without wading into the legal back-and-forth, I mention this point only to note that there is no economic basis for preferring (or not) a market definition based on the number of distinct chemical compounds it contains. If antitrust markets are to have any economic meaning, they should be defined (as the Supreme Court has said they should) based on reasonable substitutability of use by consumers, and, more precisely, cross-elasticities of demand. In dealing with pharmaceutical drugs, it is not unusual for a particular chemical compound—a single molecule—to have relatively unique effects on the human body, as compared to other molecules that happen to be commercially available at the same time. This is why it is unsurprising that there have been a number of pharmaceutical litigations in which the relevant market, for antitrust purposes, was defined as a branded RLD molecule together with its AB-rated generic equivalents, which is precisely the sort of market definition the State of New York urges in this case.[47]

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[46] Memorandum in Opposition to Plaintiff's Motion for Preliminary Injunction, at 43.

[47] See, for example, In Re Nexium (Esomeprazole) Antitrust Litigation, Civil Action No. 12-md-02409-WGY, United States District Court for the District of Massachusetts, *968 F. Supp. 2d 367; 2013 U.S. Dist. LEXIS 129696l 2013-2 Trade Cas. (CCH); P78,588*; In Re: Terazosin Hydrochloride Antitrust Litigation, Case No. 99-MDL-1317-Seitz/Klein (all cases), United States District Court for the Southern District of Florida, *352 F. Supp. 2d 1279; 2005 U.S. Dist. LEXIS 108; 2005-1 Trade Cas. (CCH) P74,709; 18 Fla. L. Weekly Fed. D 321*; and In Re: Cardizem CD

39. I have also considered the relevant *geographic* market for this case, and have determined it to be the United States. Based on my knowledge of the pharmaceutical industry, I am aware that buyers of drugs in any part of the United States are, generally speaking, equally willing to purchase their pharmaceuticals from sellers located in any part of the world, and sellers also have little or no preference for, or against, selling medications to buyers in any particular part(s) of the world. Transportation costs of most ordinary medications delivered in capsule or tablet form, including NMDA antagonists, are very low relative to their prices. The market, however, is not global, because (i) sellers are able to price discriminate between patients in the United States and patients outside of the United States, and (ii) there are legal/regulatory import restrictions that apply to pharmaceutical drugs. Accordingly the appropriate geographical antitrust market is the United States.[48]

VII. ECONOMIC HARM TO CONSUMERS AND PAYERS DUE TO THE PLANNED "HARD SWITCH" STRATEGY

Overview

40. Forest envisages loss of exclusivity ("LOE") due to patent expiration and limited pediatric extension exclusivity on Namenda IR on or about July 11, 2015.[49] Hence, if the Namenda IR LOE followed a conventional scenario, in July 2015 (or, if there is limited 180-day exclusivity due to a successful Paragraph IV challenge, six months after July 2015) Namenda IR

Antitrust Litigation, This Document Relates to All Actions, Master File No. 99-md-1278, MDL No. 1278, United States District Court for the Eastern District of Michigan, Southern Division, *105 F. Supp. 2d 618; 2000 U.S. Dist. LEXIS 13186; 2000-1 Trade Cas. (CCH) P72,940.*

[48] See, e.g., U.S. Dept. of Justice and Federal Trade Comm'n, Horizontal Merger Guidelines (Aug. 19, 2010), sec. 4.2.

[49] Forest's Memorandum in Opposition to Plaintiff's Motion for Preliminary Injunction, at 6-7. Pediatric studies extended Forest's exclusivity date to Oct. 11, 2014, giving ten manufacturers the right to begin selling generic memantine three months earlier, on July 11, 2014 (or earlier in "certain circumstances"), under the terms of an agreement with Forest. Five of these ten manufacturers have tentative FDA approval to sell generic memantine. Seven more "potentially may begin" selling the generic product as early as Oct. 11, 2014.

would face extensive competition from generic memantine entry. Following the pattern that is conventional in such cases, almost without exception, Forest would likely lose market share to the generics, keeping a relatively small share for branded Nemanda IR, composed of less price-sensitive buyers—i.e., patients with less price-sensitive insurance plans, or those who do not mind paying the higher co-payment for the branded Namenda IR product. Forest launched Namenda XR (a once-daily dosing frequency, in contrast to the twice-daily dosing of Namenda IR) in June 2013, and hopes to be able to launch its fixed-dose combination product with donepezil and Namenda XR (called Namenda FDC) in early 2015.[50] At a January 2014 earnings call, Forest CEO Brent Saunders described this decline in the Namenda franchise revenues from LOE as a "cliff," and said that it could reduce annual revenue from Namenda IR from $1.6 billion to roughly $200 million.[51]

41. Based on the documents and data I have reviewed, it is clear that Forest considered various strategic alternatives to mitigate the conventional "patent cliff" scenario sketched above, because the company has patent protection on both Namenda IR and Namenda XR, but only the Namenda IR product faces imminent LOE. Such strategies are often referred to as "product-hopping." The conventional form of such a strategy (a "soft switch") would be for Forest to dramatically reduce its marketing expenditures on the IR product, and possibly even raise the price of the IR product, in advance of LOE, in an effort to promote switching by patients who take the IR product (which faces imminent LOE) to the XR product (which does not).

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[50] Meury Exh. 18, p.8 (FRX-NY-01642557, at -01642564); Meury Exh. 19, p.4 of 31.

[51] Meury Exh. 18, p.8 (FRX-NY-01642557, at -01642564.

42. However, it appears that this strategy was rejected by Forest, in favor of a "hard switch" strategy that essentially would make the Namenda XR product unavailable, or nearly so, prior to LOE, thus forcing the overwhelming majority of IR takers to switch to the more patent-protected XR form of the drug.[52] In my experience, this hard-switch strategy—in which a drug is pulled from the market in the absence of any special health or regulatory concerns, when the drug was profitable, and when there were no generic or over-the-counter versions available—is extremely unusual. I cannot say authoritatively that it is completely unprecedented in the recent past, but it may be. As an academic and consultant who has studied the pharmaceutical industry for many years, I am familiar with no other examples.

43. I am not alone in this view, [redacted][51]

[52] I say "the overwhelming majority," rather than "all," for two reasons. First, as [redacted] there is likely to be some "disruption," i.e., patients who leave memantine altogether when Namenda IR is withdrawn, for various reasons. Second, there may still be ways to obtain Namenda IR even after the hard switch—either by taking Namenda IR in its liquid form or, possibly, by using the "limited distribution" through a specialty pharmacy that Forest has said it is implementing. For reasons discussed below, these channels are expected to apply to an insubstantial number of patients. Therefore, for purposes of assessing overall competitive effects of the hard switch, one can, to a good approximation, regard it as tantamount to total withdrawal of Namenda IR.

[53] Meury Inv. Hearing Exh. 14, FRX-NY-01622854 through FRX-NY-01622856.

[redacted][54] [redacted]

[redacted][55])

Foreseeable effect of the hard switch: Foreclosing or forestalling generic competition

44. It is my opinion that Forest's unusual "hard switch"—i.e., the cessation of manufacturing and marketing Namenda IR prior to its LOE in July 2015—would have a number of foreseeable likely effects on competition. One of these is that it would substantially impede and harm generic competition for memantine sales. As alluded to above, the primary mechanism by which generic competitors enter a pharmaceutical market is—and at least since the passage of the Hatch-Waxman law, has been—through the combined effect of state generic-substitution laws and cost-reduction efforts by payers.

45. In some states (including Plaintiff the State of New York), state generic substitution laws actually compel pharmacists to switch patients from the branded drug to a generic version that is AB-rated to the branded drug. The one significant exception to this would occur in cases where the physician indicates that only the branded drug is to be dispensed—often by writing "Dispense as written" or checking an equivalent box on the prescription form. In my experience it is rare for physicians to take this extra step, or for patients to ask them to do so. Of course, the generic form of Namenda IR will be AB-rated to branded Namenda IR, even though it will not be AB-rated to branded Namenda XR. Therefore, in states with such mandatory substitution laws, under conventional scenarios one can reasonably expect that at least 90% of the Namenda IR prescriptions would be transferred to the generic IR form upon LOE.

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[54] Meury Inv. Hearing 21.

[55] Meury Inv. Hearing Exh. 14, FRX-NY-01622854 to -856.

46. In many other states, pharmacists are permitted, but not required, to substitute the generic form of a drug for the branded form to which that generic is AB-rated. However, as a practical matter, it is well-known that major health insurers routinely require generic substitution of AB-rated equivalent drugs by the pharmacist. Again, the relevant laws typically do allow a physician to require that the brand-name version be dispensed to a particular patient, but only by taking the extra step of indicating "Dispense as written" on the prescription, which, as noted, is rare. Therefore, because so many patients have their medications paid for through a large insurer, generic substitution rates in the "permissive substitution" states are typically similar to those in the mandatory substitution states.

47. In his declaration, Forest's expert Pierre-Yves Cremieux claims that 20 states have generic substitution laws that give the pharmacist discretion in substituting a generic for a brand-name drug to which the generic is not AB-rated.[56] However, a closer look at the source cited by Dr. Cremieux for that proposition—a table called "State Regulations on Generic Substitution"—reveals that, of the states listed by Cremieux, only two (Minnesota and Vermont) would likely allow generic substitution between generic memantine (IR) and Namenda XR, and four others (Nebraska, Washington, North Dakota, and Oklahoma) might do so, depending on one's interpretation of the rule as set forth in Cremieux's source.[57] These six states (a group that already errs on the side of overinclusion) account for 6% of the U.S. population.

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[56] Cremieux Decl., para. 31 & n.49.

[57] The main reason for excluding the other states listed by Cremieux is that their rules tend to require that the quantities and/or dosage forms of the generic and branded drug be the same, which is not the case for generic memantine (IR) and Namenda XR: the former is marketed in 5 and 10 mg tablet dosage formulations, and the latter in 7, 14, 21 and 28 mg capsule dosage formulations. Moreover, the capsule formulation can be split in half and sprinkled over apple sauce, unlike the tablet formulation. Also, tablets and capsules are not the same "dosage form."

48. For the above reasons, in a typical "patent cliff" scenario that occurs at LOE of a branded drug, it is not uncommon for the generic share of the molecule's total outstanding prescriptions (i.e., the generic efficiency or conversion rate) to be above 80% at three months after LOE, to increase to 90% or more at twelve months following LOE, and then to maintain or slightly grow that share by the 24th month after LOE. By contrast, if Forest discontinues Namenda IR before LOE, it is reasonable to suppose that roughly [redacted] or more of Namenda IR takers would switch to Namenda XR, and approximately none would shift to generic memantine (IR) – since the switch would, by definition, occur before any generics were on the market. [redacted] [58]) Therefore, immediately following the hard switch, in the conventional scenario generics would have [redacted] or more of the existing Namenda IR prescriptions, while under the "hard switch" scenario generics would have approximately none, since the switch would by definition occur before any IR generics were on the market.

49. Generic entrants would likely gain some sales over time, following their July 2015 launch. For example, a relatively recent public forecast by Forest's CEO suggests that, in a hard-switch scenario, over time something in the range of 5% to 30% of Namenda XR subscribers would shift to the generic IR form on their own.[59] Still, denial of effective access to 70%-plus of the "installed base" of Namenda IR users would effectively foreclose generic drug makers from their primary, and best, means of effective entry. Of course, Forest could gradually build sales as new Namenda users entered the market, and their doctors were able to make a fresh choice between Namenda XR and the generic. [redacted]

[58] Meury Exh. 16 (FRX-NY-01566912, attachment, at slide 23).

[59] Saunders Exh. 4 (Forest Laboratories FQ4 2014 Earnings Call Transcript, p. 13 of 21.

[redacted][60]) But, even assuming the generics win half of these prescriptions, that amounts to just an [redacted] share over the first two years (i.e., half of the [redacted] of new prescriptions that began post-LOE.[61])

50. In short, because of the "hard switch," generic entrants would be substantially denied access to their primary, and best, means of entry. Rather than having an immediate infusion of sales, representing the large majority of all of the Namenda IR patients at the time of LOE, generic entrants would need to settle for a relatively small, albeit gradually growing, share of the business. Notably, the second-best method by which a generic entrant can develop a prescription base—through marketing efforts—is *also* unavailable in this case, because there will likely be multiple generic entrants from the outset, so marketing efforts by any one of them would be irrational, as they would stimulate sales that would go to all of the generics, not just the one paying for the marketing. (In fact, the generic firm doing the marketing would probably secure an unusually small slice of the business, since its marketing costs, and thus its prices, would tend to be higher than those of the generics that free-ride off the firm's marketing efforts.)

51. The competitive harm, however, comes not from the fact that generic drug makers will be less successful. Generic firms may still convert 90-or-more percent of the Namenda IR prescriptions to generic memantine IR, but the size of the base on which conversions from branded IR to generic IR can occur will have been eviscerated. The harm therefore derives from the fact that far fewer patients will get their memantine from a generic company than would have

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[60] FRX-NY01609009, at -9017.

[61] To explain: Assuming the [redacted] number is accurate, if there were [redacted] existing Namenda users at time 0, roughly [redacted] of them would still be taking Namenda at the end of year 1, and [redacted] would be new users. During the second year, [redacted] more new users would arrive, and the group from the end of year 1 will have eroded to [redacted] of its size to accommodate them. Thus, the [redacted] who arrived in year 1 will have shrunk to 16. That 16, plus the 20 that arrived during year 2, comprises the [redacted]. (More simply [redacted] is [redacted].)

been the case absent the hard switch. These people, at least in the early years post-hard-switch, will have effectively been denied a choice, or, more accurately, their cost of exercising a choice will have been increased strategically by Forest.

Foreseeable effect of the hard switch: Competitive harm quantified

52. The most recent authoritative Forest estimate I know of that refers to the rate at which Namenda XR patients are expected to switch to generic memantine (IR) following the hard switch was announced by William Meury, Executive Vice President of Sales and Marketing, on Forest's F4Q 2014 earnings call. The relevant portion of the colloquy went as follows:

> **Elliot Wilbur (Needham & Company):** . . . Just a couple of quick questions around the MDX 8704 franchise. Reasonable to expect that at some point in time next year there will be generic versions of Namenda on the market. And obviously, there's not an AB-rated substitutable drug that's going to be available. But how do you guys think about leakage when you build your longer-term models? Certainly, would assume it would be relatively small, but is 5% to 15% a reasonable assumption? . . .
>
> **Brenton Saunders (Forest CEO):** I'll turn it over to Bill in a second. I think in terms of generic IR, we do get the pediatric extension as we expect. The generic should enter the market around July of 2015 is the date of the settlement date. So it's pretty much set in stone. I think you want to talk a little bit about the conversion and leakage rate?
>
> **William Meury (Forest Executive Vice President of Sales and Marketing):** Yeah. If you look at the XR formulations that face generic alternatives, there's a fairly wide range of erosion. It can be as low as you point out in the 5% to 10% range. It could climb higher to 30% or more. And what I would keep in mind with Namenda XR is that it is a relatively fragile population of patients. We think that the dosing schedule here is particularly relevant and that we should preserve a good portion of our Namenda cells [sic]. Now I don't think we'll be at the lower end of the range necessarily, but I don't think that we'll exceed the high end of the range either."

53. Mr. Meury is referring to other "XR" products that have existed in the past, and the rates at which patients are expected to switch from Namenda XR to generic IR, based in part on studying historical analogs. Mr. Meury's view is that this rate of "leakage"—what Forest often calls "erosion" to generic IR—is expected to be somewhere in the range from 5%-10% on

the low end, to 30% on the high end. Mr. Meury also suggests that patients will be averse to switching yet again because they are a "relatively fragile population" and will be reluctant to change their pill-taking schedule yet again, once they have become habituated to taking the medication once a day. When he says, "Now I don't think we'll be at the lower end of the range necessarily, but I don't think that we'll exceed the high end of the range either," he can only be referring to the 5%-10% lower end, and the 30% upper end, to which he had referred to a moment earlier. Thus, some number between, say, 5% and 30% would seem appropriate.

54. Another strong piece of evidence regarding the expected erosion rate is a document [redacted][62] [redacted] This is [redacted] with the 5%-30% range used by Meury at the earnings call nearly two years later. [redacted][63]

55. For the reasons given above, I am comfortable using the hypothetical erosion rate of [redacted]30%[redacted] to err on the side favoring Forest's position in the Litigation, while staying

[62] FRX-NY-01673963, at slides 6-8.

[63] FRX-NY-01673963, at slide 7.

within the range of what is reasonable.[64] If one adopts the 30% (i.e., most Forest-friendly) figure from this range, then one must conclude that, even *two years* after LOE, about 70% of the patients who were originally on IR would not only have been "hard switched" to XR, but would still be taking Namenda XR. To view it another way, instead of roughly 90% of these prescriptions switching to generic, as would ordinarily occur, roughly 30% would switch to a generic. Present-day IR users would therefore be only one-third as likely to be taking generic memantine (IR) two years after LOE than would have been the case absent the forced switch.

56. The highest estimated two-year erosion rate I know of is the [redacted] figure found in [redacted][65] [redacted]

57. Even if one were to use a [redacted] erosion rate, that would mean that of those who were taking Namenda IR at the time of the hard switch, by the end of the second year following LOE generics would have captured [redacted] of the volume, as opposed to roughly 90%—still a material reduction in competition.

58. [redacted]

[64] I realize the that Forest may take the position that certain physician, pharmacist, and caregiver surveys it has done lead to the conclusion that erosion rates from Namenda XR to the generic would be higher. However, having considered the relevant documents I do not share that view.

[65] Meury Exh. 16 (FRX-NY-01566912).

[redacted]

59. [redacted]

[redacted]

FIGURE 3[66]

60. [redacted]

61. The harm to consumers and payers is material as well. To estimate the magnitude of this harm, I undertook a simple approximate calculation, using the share numbers from Exhibit 3 – [redacted] – and the branded and generic price assumptions made by Dr. Cremieux in his calculations [redacted] In particular, I assume, as Cremieux did, that branded Namenda XR costs [redacted]; Of that [redacted] is paid by the patient in the form of copayments at the pharmacy,

[66] FRX-NY-01639146.

and the remaining [redacted] is paid by the health plan. Like Cremeiux, I assume that generic memantine (IR) costs roughly [redacted] split between the plan (which pays [redacted]) and the patient (who pays a [redacted]). As a reasonable approximation, I assume that the price paid by the Namenda FDC users in the hard-switch scenario is roughly the same as the price paid by the Namenda XR users in the hard-switch scenario. (I note that only a small number of people are added to the FDC category on account of the hard switch.)

62. These assumptions imply that for every additional day of treatment for which a patient uses branded Namenda XR (or the FDC) instead of using generic memantine (IR), the additional cost is [redacted] or [redacted]. This additional cost is divided between (i) the health plan, which pays an extra [redacted], or [redacted]; and (ii) the patient, who pays an additional ($1.70 − $0.33), or $1.37. These calculations are summarized in Table 3 below.

TABLE 3

APPROXIMATE CALCULATION OF ADDITIONAL COST PER PATIENT PER DAY OF CHOOSING NAMENDA XR OVER GENERIC MEMANTINE (IR)

[redacted]

63. Multiplying the "excess costs" per day shown in the third column of Table 3 by the number of patient-days that are successfully shifted by Forest from the generic to the branded XR product, due to the "hard switch," results in an estimate of total excess payments on account of the hard switch. (As an approximation, I assume that the very small number of people who would remain on branded Namenda IR in the absence of the hard switch will reflect a cost profile similar to that of the Namenda XR patients—even though, in fact, the two will differ somewhat.) I do not use the numbers of patient-days given in Figure 3, because Figure 3 [redacted] Accordingly, erring in Forest's favor, [redacted] so that it can be compared on an apples-to-apples basis with the hard-switch scenario. In this model, the number of patient-days of generic memantine (IR) under the hard switch is [redacted] and the number of generic patient-days absent the hard switch, scaled down to account for disruption, is [redacted]. The difference, [redacted], is the approximate number of patient-days that would have been shifted from generic memantine (IR) to Namenda XR (or FDC) on account of the hard switch. (Again, because of the method of correcting for disruption, this is really a lower limit, not a point estimate.) Multiplying the "excess cost" figures in Table 3 by this number of patient-days that are forced from the generic product to the Namenda XR product, one finds as follows:

Quantifying the Harm from Scenarios Based on Figure 3 above

- Additional cost to plans imposed by the hard switch [redacted]
- Additional cost to Alzheimer's patients imposed by the hard switch [redacted]
- Additional total cost (plans + patients) imposed by the hard switch [redacted]

This can be graphically depicted as follows (Figure 4):

FIGURE 4
QUANTIFICATION OF OVERPAYMENT
DUE TO FOREST'S HARD-SWITCH STRATEGY

[redacted]

64. [redacted] It will also cost health plans approximately [redacted] much of which will eventually be reflected in higher insurance premiums borne by individuals, employers, and governmental entities.

65. Another particularly instructive data point is provided by the [redacted]

[redacted]

[redacted][67] [redacted] is a large generic pharmaceutical manufacturer and distributor that is one of the five ANDA applicants whose applications to sell generic memantine (IR) have been tentatively approved by the FDA, and that is contemplating entering the market in July 2015. [redacted]

66. The results are stark. [redacted] two-year "erosion rate" of 30% that was discussed above is roughly in the right range.[69]

[redacted]

[redacted]

[redacted] "erosion" from Namenda XR to generic memantine (IR) of roughly 37%.

FIGURE 5

67. The fact that Forest is now apparently planning to make Namenda IR available through "limited distribution" of some sort does not change my views concerning harm to competition and consumers. CEO Brent Saunders made it clear at his deposition that such limited distribution would only be for cases of "medical necessity," as determined by the

patient's physician,[70] and such cases are expected by Forest itself to represent well under [redacted] of Namenda IR patients.[71]

VIII. THERE IS NO LEGITIMATE BUSINESS JUSTIFICATION FOR WITHDRAWING NAMENDA IR PRIOR TO LOSS OF PATENT EXCLUSIVITY

68. As I understand it, a core issue in this Litigation is the degree to which the "hard switch," or "forced switch," strategy is being pursued by Forest merely to exclude or frustrate generic competition, as distinct from any legitimate business motive, such as quality improvement, service improvement, or the achievement of cost efficiencies. Having considered the evidence, I have formed an opinion that, in fact, there is no plausible business rationale for the hard switch, aside from the frustration of generic competition. In simplest terms, if it were not for the fact that generic IR competitors are poised to enter the market in July 2015, it would make no economic sense for Forest to discontinue manufacturing and marketing Namenda IR prior to July 2015.

69. In earnings calls with investors and Wall Street analysts, Forest's CEO, Brenton L. Saunders, has touted the long-term benefits of Forest's implementation of the hard switch strategy of preemptively withdrawing Namenda IR from the US market prior to its LOE on July 11, 2015. It is very clear from Saunders's comments to Wall Street, such as the following, that the chief purpose of the strategy is to impair generic competition:

- On a 1/7/2014 call or meeting,[72] Mr. Saunders said, "We are actively considering and debating a hard switch . . . If you kind of look at the timing of [Namenda] IR, IR will go generic in July of 2015. And so the sweet spot for a switch would be in the fall, and so that's kind of how we're thinking about it."

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[70] Saunders Dep., 338-40.

[71] Kane Dep. 40-41.

[72] Meury Exh. 17 (FRX-NY-01642557, at -564).

- On the same call/meeting,[73] in response to a follow-up question about "drift back" from Namenda XR to generics following the hard switch, Mr. Saunders said, "What we're trying to do is put up barriers or obstacles to go from a [patent] cliff to a steady decline, right, a steady managed decline over four or five years versus in three months a $1.6 billion [revenue] product is $200 million."
- In response to the same follow-up question, Saunders said, "And, look, generic Namenda IR is going to take a lot of the new starts, but it's about maintaining the base that you have now and fighting for some of those new starts with the once-a-day convenience [of XR] or the combo pill [that combines Namenda XR and donepezil]."[74]
- On a 1/21/2014 earnings call to discuss Forest's Q3 2014 results, now three weeks before the public announcement of the forced switch, Saunders explained, "And we believe that by potentially doing a forced switch, we will hold on to a large share of our base users, then we will fight for new Rxs."[75]
- On the same 1/21/2014 earnings call, Saunders continued as follows: "So once – if we do the hard switch and we've converted patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing Rxs. They don't have the sales force, they don't have the capabilities to go do that. It doesn't mean that it can't happen, it just becomes very difficult. It's is an obstacle that will allow us to, I think, again, go in to a slow decline versus a complete cliff."

70. As an industry expert, who has been doing research and consulting in the pharmaceutical marketing arena for many years, I interpret quotations such as these as convincing evidence that Forest's purpose in committing to the hard-switch strategy was not to make Namenda IR, or Namenda XR, a better product, a cheaper product, or a lower-cost product, nor was it to improve services in any way. Rather, it was to erect, in Mr. Saunders's words, "barriers or obstacles" to the switching of existing Namenda IR prescriptions to generic

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[73] Id.

[74] Meury Exh. 17 (FRX-NY-01642557, at -565) (words in square brackets no in original).

[75] Meury Exh. 19 (Forest Laboratories Management Discusses Q3 2014 Results – Earnings Call Transcript, Jan. 21, 2014, available at http://seekingalpha.com/article/1957941-forest-laboratories-management-discusses-q3-2014-results-earnings-call-transcript, last accessed Nov. 2, 2014), at p.13 of 31.

substitutes—switching that would occur in very substantial numbers if patients, caregivers, and payers were given the unfettered choice, as is conventionally the case.

71. [redacted] give me no reason to believe there is any significant purpose to the hard-switch strategy *other than* the avoidance of generic competition for the [redacted] of Namenda IR users that will exist at the time of LOE.

72. The short-term profit effect of undertaking the hard-switch strategy is clearly negative for Forest. [redacted] The hard-switch strategy is expected to *reduce* Forest's profits in the short term, i.e., in the period prior to LOE and generic entry.

73. [redacted][76] [redacted][77]

[76] Meury Exh. 16 (FRX-NY-01566912, at -913, slide 5). [redacted]

74. [redacted] So, in the end, he believes Forest would [redacted] due to patients leaving Namenda entirely, but would [redacted] price/mix—which is largely explained by the fact that Forest is charging less for Namenda XR than it has charged for Namenda IR (according to Plaintiff's expert economist, Pierre-Yves Cremieux, not just a lower WAC list price, but additional rebate discounts amounting up to 20 percent),[78] and so the "forced switch" actually forces patients from a higher-priced product to a lower-priced product:

> Mr. Stock: So it is going – you're going to [redacted] in the first fiscal year as a result of a forced switch strategy?
>
> Mr. Saunders: [redacted][79]

75. Thus, it is clear to me that the forced switch strategy would be—and is understood by Forest to be—profit-destroying for Forest in the short run, i.e., prior to LOE. [redacted]

[78] Declaration of Pierre-Yves Cremieux, October 21, 2014, ¶53, pp. 23-24.

[79] [redacted]

[redacted] And so on. The full financial model is captured in Table 4 below.

TABLE 4

[redacted]

76. [redacted] As one can see from Table 4, [redacted]

[redacted] In short, the hard switch is a very attractive and lucrative business strategy for Forest.

77. In his deposition, Forest CEO Brent Saunders confirmed the nature of the hard-switch investment:

> Mr. Stock: How much money does Forest save by discontinuing Namenda IR?
>
> Mr. Saunders: We don't save any money, we actually lose money; 2015 we will lose money.
>
> Mr. Stock: Then I don't understand how it conserves resources to discontinue Namenda IR.
>
> Mr. Saunders: Because IR – sorry, because XR, the newer, more innovative medicine, should have a longer patent life as should the fixed dose combination. That's the rewards for innovation that we get.[80]

78. During his deposition, Mr. Saunders also noted that there would be certain cost savings associated with ceasing the supply of Namenda IR—such as savings on production and distribution costs, trucking costs, and account management costs.[81] But when he was asked, [redacted][82]

79. I believe it is clear from the above evidence that the forced switch is expected to reduce Forest's profits in the short run. It is also clear that this short-run sacrifice of profits is expected by Forest to be rewarded handsomely in additional profits in the medium term. These profits will not result from any material decrease in costs—[redacted] Nor will they result in

[80] Saunders Dep., 224-25.

[81] Saunders Dep., 225.

[82] Saunders Dep., 226.

any increase in the quality or service associated with either Namenda XR or Namenda IR. Rather, these excess profits are expected to result from moving present-day Namenda IR users to Namenda XR prior to LOE, so that a smaller number of these patients will switch to generic Namenda IR than would otherwise be the case, and those who do switch will, on average, take longer to do so and at higher cost to them and/or their insurer.

80. The competitively neutral or pro-competitive reasons offered by Mr. Saunders for the hard switch strategy are simply not credible. The notion that Forest is discontinuing Namenda IR, its top-selling drug, because "we have to focus our resources on our newest innovation"[83] does not make sense. Increased "focus" of a company's resources on its more profitable products is certainly a legitimate goal. But that goal can be attained—and typically is attained by brand-name drug companies with a drug that faces generic entry—without withdrawing that drug from the market. As almost all other branded companies have done when facing near term LOE, Forest could have simply instructed its sales force to stop "detailing" and promoting Namenda IR. If the company wanted to preserve its manufacturing "focus," it could likely contract with another firm to co-market Namenda IR between now and July 2015.

81. It is obvious that reducing manufacturing costs is not a major goal of the hard switch. If it were, Forest could likely contract with one of the generic firms approved by the FDA to sell memantine to provide backup manufacturing capacity, or even become an authorized supplier in a co-marketing arrangement with Forest, thereby letting Forest personnel shift their focus to other Forest products.

[83] Saunders Dep., 224.

82. Withdrawing Namenda IR from the market would not be expected to have any material net impact on shipping, trucking or inventory costs, since the total size of the Namenda franchise is largely unchanged by the hard switch, as sales reductions in Namenda IR are nearly offset by increases in sales of Namenda XR. Regarding costs to pharmacies for stocking and managing inventory: In today's world these details are automated and electronically tracked. In the era of Walmart and Amazon, it is simply not plausible to argue that the tracking of a few additional stock-keeping-units' worth of tiny medicine tablets presents logistical challenges that would actually "move the needle" on any sort of corporate decision by a pharmaceutical company the size of Forest, now part of Actavis.

83. In summary, I see no possible business justification for the hard-switch strategy, other than the increased net present value of operating income accruing to Forest as a result of its diminishing competition from generic memantine. To the extent that, because of the hard switch, generic memantine captures a smaller share of the NMDA antagonist market than it would have done in the absence of the hard switch, payers and patients will be paying higher prices for their NMDA antagonists than they would have done in the absence of the hard switch. Indeed, even the prices for the (smaller) generic portion of the market may be higher due the hard switch, because fewer generic entrants will succeed, and fewer may enter in the first place—leaving the generic market no more competitive, and possibly less competitive, than it would have been absent the hard switch.

84. Finally, regarding benefits to patients: While I agree that for many patients there is likely a preference for a once-daily versus a twice-daily formulation of Namenda, there is no reason to believe that this is the case for *all* Namenda IR consumers, because, among other things, switching from twice-a-day to once-a-day requires a disruption in routine for elderly,

vulnerable patients and their caregivers. The burden of this disruption will vary across patients and their caregivers. However, what will not vary is the preference for *no* disruption over *two successive* disruptions: one from Namenda IR to Namenda XR, and a second one from Namenda XR back to generic IR for patients who choose to avail themselves of the lower-cost generic IR alternative. Even setting aside switching costs, some patients may have a positive preference for twice-daily use—for example, because of dietary or metabolic factors due to possible adverse reactions from concomitant utilization of other medicines (some of them likely also being twice daily, given the high proportion of polypharmacy among seniors, especially seniors with symptoms of the Alzheimer's type); and favorable and consistent experience from taking Namenda IR. Thus, it is plausible to believe that there is a non-trivial number of patients who have a preference for twice-daily Namenda. Indeed, even with the very substantial price discounts Forest has given Namenda XR relative to Namenda IR, most Namenda IR takers have not yet converted to Namenda XR. These patients will no longer have the opportunity to take their preferred Namenda IR medicine due to the forced switch, and they will thus be harmed.

85. I am aware that Forest sponsored opinion surveys of pharmacists, physicians, and caregivers. These surveys do not change the conclusions discussed above. I am not aware of any comparable surveys Forest has conducted of private or public payers. As an economist, I am generally more persuaded by preferences revealed in actual market transactions or projections made by sophisticated market participants, than by opinion surveys.[84]

IX. THE CLAIM THAT THE RELIEF SOUGHT BY THE STATE OF NEW YORK WOULD CONSTITUTE FREE-RIDING IS WITHOUT MERIT

[84] *See* Hausman Dec., para. 19 ("Economists place considerable weight on actual behavior in comparison to claims made in declarations that are not substantiated by actual behavior.")

86. Forest's economic expert Prof. Hausman suggests that granting the relief sought in this case would somehow encourage "free-riding," a well-known economic phenomenon that can lead to inefficient results.

87. First, though I do not claim to be a legal expert, it seems to me that this particular argument has no place in an antitrust case. In antitrust contexts, the reduction of "free riding" is often held up as a rationale for certain commercial restraints that might otherwise be suspect. For example, when a manufacturer awards "exclusive territories" to its retailers, it is certainly making the downstream market for the sale of its goods less competitive, in one way. But it may also be preventing free-riding by low-priced, low-service retailers who locate their businesses near the higher-quality stores, in the hopes that the high-service stores will educate the public about the product, then customers will simply drive down the block and buy it for less from the low-service store. In such a case, exclusive territories may enhance competition, by preventing such free-riding, thereby giving store owners the proper incentive to invest in providing good service.

88. The free-riding cited by Prof. Hausman is not of that variety. Forest was definitely *not* trying to solve an ongoing free-rider problem when it decided to implement the hard switch. It could not have, because the supposed goal of eliminating the free-riding—incentivizing an efficient level of R&D investment in Namenda IR—had already been done years ago. Nothing Forest does now can change the quantity of resources that Merz initially put into Namenda IR to get the drug off the ground, or that Forest later put into it to make it clinically available in the United States.

89. Rather, Forest's free-riding claim is a larger public policy point—that if Forest is not allowed to extend the effective life of Merz's patent on Namenda IR, companies

manufacturing *other drugs in the future* will not have the proper incentives to innovate. It seems highly suspect to try to balance the anticompetitive effects on one group of consumers, against claimed future pro-competitive effects on other groups of consumers, consuming entirely different products—products that do not yet exist!

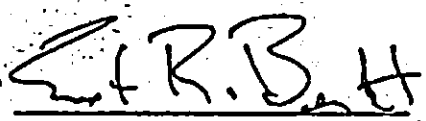
90. Even on its own terms, Forest's free-riding claim is ill-conceived. First, Forest did not do the initial the discovery R&D for Namenda IR. Merz apparently did. And when Merz made its R&D investment decision, it could not have known that its licensee would develop an XR formulation and attempt a hard switch. (That, after all, is the only way in which Merz's *ex ante* incentives could possibly have been affected.)

91. More basically, though, Forest seems to be ignoring the fundamental tradeoff embodied in the patent law and the "grand bargain" of Hatch-Waxman. During a patent's term, a patentee is given artificial protection against the usual reverse engineering and copying. In exchange, the patentee must *publish* its invention, so that when the patent term expires the public may "free ride" by practicing the patent. The free-riding that follows the end of the patent term has been found, as a policy matter, to be the appropriate *level* of free-riding – it is an explicitly sanctioned amount of free-riding—and it is granted to the public only at a price: the price of not being able to copy, and having to pay monopoly rents, during the patent's term.

92. Forest appears to want it both ways. It has benefitted for years from the artificial protection from market forces afforded by the patent system—including special Hatch-Waxman extensions of the patent's term for patent-term restoration and pediatric exclusivity studies. Then, when the monopoly profits had been duly collected, and the patent cliff was looming, Forest suddenly realized that completely unremarkable generic entry would suddenly constitute "free-riding," and unduly undermine innovation. If Forest's attempt to shave down the patent

cliff is "free-riding," then practically every case of generic entry in the United States is free-riding as well. Fundamentally, Forest appears to want to benefit from the Hatch-Waxman scheme without paying its price. If the term "free-riding" can be applied to any conduct in this case, it is Forest's own.

I declare under penalty of perjury that the foregoing is true and correct.



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November 5, 2014